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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/528,682	PIZZA ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/24/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-32* is/are pending in the application.

4a) Of the above claim(s) *30-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's IDS filed on 08/24/2005 has been entered.

Rejections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

Status of the claims

2. Claims 7-32 are pending.

Pursuant to previously filed response to election of species (filed 02/25/2003), polynucleotides that encode polypeptide numbered relative to SEQ ID No. 1 are elected. Claims 30-32 remain withdrawn from consideration as drawn to non-elected species.

Drawings

3. As before, it is noted that the previous Office actions objected the proposed drawing Fig. 12, as well as correspondent amendments to specification, because it introduced new matter. The original disclosure does not support the showing of sequences as resented on Fig. 12.

As stated previously, Examiner disagrees with applicant's arguments on this matter for the following reasons:

Examiner agrees with the applicant's argument that all references cited in the specification were addressed as incorporated by reference. However, as addressed previously, the information on SEQ ID Nos 1-4 presented in the reference is essential material as it is being directly claimed in the amended claims. "Essential material" may not be incorporated by reference to non-patent publications. See MPEP 608.01(p). Applicant cites MPEP 608.01(p).2. as instructing to amend the disclosure to include material incorporated by reference. This part of MPEP 608.01(p), however, addresses whether filing date of an application wherein essential material is improperly incorporated by reference will be affected because of the reference. More general issue is whether "essential material" may or may not be incorporated by reference to non-patent publications. In this regard, MPEP 608.01(p) states the following:

See beginning of the section:

> While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques, where necessary, as to enable those persons skilled in the art to make and utilize the invention.
> Specific operative embodiments or examples of the invention must be set forth. Examples and description should be of sufficient scope as to justify the scope of the claims. Markush claims must be provided with support in the disclosure for each member of the Markush group. Where the constitution and formula of a chemical compound is stated only as a probability or speculation, the disclosure is not sufficient to support claims identifying the compound by such composition or formula.

And see MPEP 608.01(p).I.A (emphasis added):

> An application as filed must be complete in itself in order to comply with 35 U.S.C. 112. Material nevertheless may be incorporated by reference, Ex parte *>Schwarze<, 151 USPQ 426 (Bd. Ape. 1966). An application for a patent when filed may incorporate "essential material" by reference to (1) a U.S. patent, (2) a U.S. patent application publication, or (3) a pending U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) describe the claimed invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode (35 U.S.C. 112). In any application which is to issue as a U.S. patent, ***essential material may not be incorporated by reference to*** (1) patents or applications published by foreign countries or a regional patent office, (2) **non-patent publications**, (3) a U.S. patent or application which itself incorporates "essential material" by reference, or (4) a foreign application.

The material applicant is attempting to incorporate is a non-patent publication.

Second, nowhere in the specification applicant indicated possession of mutants of the particular sequences described in the Domenighini reference. The Domenighini reference itself is used in specification not to direct to particular sequences, but to direct to one particular residue of interest that this suggestion suggests to mutate. The disclosure as filed addresses strains of LT in general (p. 5, lines 5-7) and does not reduce the genus to particular species addressed in Domenighini. Applicant reiterates the specification, p. 5, lines 25-31, to argue that the specification cites the reference to show full-length sequences of LT-A proteins. Examiner, again, disagrees: the only mention of the Domenighini reference is to point that "residue to be mutated is that which corresponds to Ala-72 as defined for LT-A in Domenighini (p. 5, lines 27,28), 9X$ Xlt2106X to point at location of the Ala residue, not to a particular sequence.

Specification

4. The amendment filed 02/08/2005 is repeatedly objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no

amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The listing of sequences SEQ ID Nos. 1-4 constitutes new matter for the same reasons as their description in the form of Fig. 12 – see the preceding objection to the Drawings.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 U.S.C. § 112, first paragraph.

5. Claims 7-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

There is no description of polypeptide comprising SEQ ID No. 1 with a mutated Ala72 residue as now claimed. Specification does address Arg72 mutant of an LT-A polypeptide in general (p. 41,42, for example, demonstrates method of making) but does not demonstrate possession of a particular polypeptide SEQ ID No. 1 as now claimed. See arguments in the objection to the Drawings and Specification above. All that is described in specification as filed are LT-A polypeptides in general. See MPEP 2163.05:

> The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) ("If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see

what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.")

Note that all Domenighini reference was used for - in the much recited section of specification (p. 5, lines 25-31) - is to point that "residue to be mutated is that which corresponds to Ala-72 as defined for LT-A in Domenighini (p. 5, lines 27,28), i.e., to point at location of the Ala residue, not to a particular sequence. Nowhere does specification as filed demonstrates possession polypeptide SEQ ID No. 1 or polynucleotides encoding thereof. Neither there is a description of polynucleotides of conjugates addressed in claims 8-9.

6. This is an RCE of applicant's earlier Application No. 09/528682. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb